



Bristol-Myers Squibb Company

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

BRISTOL-MYERS SQUIBB  
 PHARMACEUTICAL GROUP  
 P.O. BOX 191  
 NEW BRUNSWICK, NJ 08903  
 (908) 519-3843

DATE: 4-8-93

NDC 0003-0445-40



Product Identification: **Gastrografin** 120 ml

Chemical Names (for active ingredients): Diatrizoate Meglumine and Diatrizoate Sodium

Synonym: Diatrizoate Meglumine and Diatrizoate Sodium Solution USP

How Supplied: 120 ml bottles.

Product Use: Iodinated radiopaque contrast medium for oral or rectal administration.

Chemical Family: Not applicable (Pharmacological mixture).

Molecular Formula: C11H9I3N2O4.C7H17N05 (diatrizoate meglumine)  
 C11H8I3N2O4.Na (diatrizoate sodium)

CAS NUMBER: See Section 2.

EMERGENCY CONTACTS

Health: 908-519-3843 (Monday through Friday, daytime). At other times contact Chemtrec or the local poison control center.

Transportation: CHEMTREC (800)424-9300

EMERGENCY OVERVIEW: Light yellow to dark amber aqueous liquid. May burn if involved in a fire.

2. COMPOSITION/ INFORMATION ON INGREDIENTS

*30% organically bound iodine (11g/30ml)*

COMPONENTS	HAZARDOUS (Y/N)	CONCENTRATION (w/v %)	CAS NUMBER	EXPOSURE GUIDELINE
Diatrizoate Meglumine	N	66.0	131-49-7	none
Diatrizoate Sodium	N	10	737-31-5	none
Water	N	> 1	7732-18-5	none
Present at > 0.1%:				
Saccharin Sodium	Y	0.3	128-44-9	none

Present at < 1%: Edetate Disodium; Sodium Citrate; Sodium Hydroxide; Polysorbate 80, Flavor; Simethicone.

3. HEALTH HAZARDS IDENTIFICATION

EFFECTS OF OVEREXPOSURE

Routes of Entry:

1. Inhalation: Under normal conditions exposure to this material by inhalation would not be expected to occur. However, in a situation where the liquid would be aerosolized, there may be potential for inhalation. The extent of systemic absorption of the material, if inhalation were to occur, is unknown.



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## HEALTH HAZARDS IDENTIFICATION (CONTINUED)

2. Skin contact: Exposure may occur via skin contact if gloves and protective clothing are not worn. The extent of systemic absorption of the material after skin contact is not known.

3. Ingestion: Ingestion of large quantities of this material in an occupational setting would not be expected to occur. Ingestion of trace amounts of the material might occur if material contacts hands and hands are not washed prior to eating, drinking, or smoking. Diatrizoate meglumine and diatrizoate sodium are very poorly absorbed from the gastrointestinal tract.

### Acute

Ingestion: Inadvertent ingestion of trace amounts of this liquid would not be expected to result in symptoms. At therapeutic doses, most adverse effects associated with ingestion of this formulation are mild and transitory. However, nausea, vomiting and/or diarrhea, urticaria with erythema, hypoxia, acute dyspnea, tachyarrhythmia, and anaphylaxis have occurred following ingestion of the contrast medium, particularly after the administration of high concentrations or large volumes of solution. Electrolyte disturbances may also occur. Severe changes in serum osmolarity and electrolyte concentrations may produce shock-like states. Cases of hyperthyroidism have been reported with the use of oral contrast media.

Inhalation: There is no information concerning the potential of this material to produce symptoms after inhalation.

### Skin Contact

a. Toxic: Contact with small quantities of material for short periods is not expected to produce symptoms after skin contact.

b. Irritation: The irritant potential of this material or its components has not been evaluated.

c. Sensitization: The potential of this material to act as a sensitizer (allergen) has not been evaluated.

Eye Contact: Material has not been tested for eye irritation potential. In the absence of this information, the material should be handled as a potential eye irritant.

Chronic: Gastrografin is not intended for chronic use and there is no information on the possible adverse effects associated with chronic exposure. Chronic oral exposure may produce the same range of adverse effects associated with acute ingestion (see above).

Exposure Guideline Summary: None.

Carcinogen Lists IARC: Yes NTP: Yes OSHA: No  
Saccharin is listed by IARC as a Class 2B carcinogen (inadequate evidence for carcinogenicity to humans). This product contains 0.3 wt% saccharin sodium, which is considered a possible carcinogen based on development of bladder tumors in rodents that ingested very high doses for prolonged periods.

Target Organs: No specific target organs identified.

Medical Conditions Aggravated by Exposure: Therapeutic or excessive doses may aggravate gastrointestinal disorders, electrolyte disturbances, allergies to iodine, hyperthyroidism and euthyroid goiter.



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## HEALTH HAZARDS IDENTIFICATION (CONTINUED)

Medical Surveillance Recommendation: None.

### 4. FIRST AID MEASURES

Ingestion: Seek medical attention immediately. Vomiting may be induced if person is conscious and not experiencing convulsions. Never give anything by mouth to an unconscious person.

Inhalation: Remove exposed person to fresh air. If person is not breathing give artificial respiration. If breathing is difficult administer oxygen. Get medical attention.

Skin Contact: Wash with soap and water. Get medical attention if irritation (redness, itching or swelling) develops or persists.

Eye Contact: Hold eyelids apart and flush with plenty of water for 15 minutes. Get medical attention.

Note to physicians: None.

### 5. FIRE FIGHTING MEASURES

Flash point: Not determined.

Autoignition Temperature: Not determined.

Flammability limits

LEL: Not determined.

UEL: Not determined.

Combustibility of Dusts: Not applicable.

Extinguishing Media: Use dry chemical, CO<sub>2</sub>, or "alcohol" foam.

Firefighting Instructions: Firefighters should wear self-contained breathing apparatus (SCBA), flame and chemical resistant clothing, boots and gloves. Evacuate personnel to upwind direction, remove unneeded material. Cool container(s) with water from maximum distance. Fight fire from a maximum distance or use an unmanned monitor. Move container from fire area if you can do it without risk.

Hazardous Combustion Products: CO, CO<sub>2</sub>, HI, I<sub>2</sub> (reddish-brown gas), NO<sub>x</sub>.

Unusual Hazards: None known.

### 6. ACCIDENTAL RELEASE MEASURES

Spill/Clean-up: Absorb spill with inert, material (e.g. sand, vermiculite or other non-combustible absorbent materials) and place into a closed container for reclamation or disposal. Flush residual spill area with water to process sewer if allowable under National, State, or local permits and regulations.

### 7. HANDLING AND STORAGE

Handling Precautions: No special requirements.

Container Requirements: Store in the container provided.



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## HANDLING AND STORAGE (CONTINUED)

Storage Conditions: Store at room temperature (20-25 degrees C). Avoid excessive heat. Protect from light.

### 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Ventilation Requirements: None beyond good room ventilation normally required; local exhaust ventilation is recommended if significant dust concentrations are generated.

Respiratory Protection: When engineering controls are not sufficient to control exposure, wear NIOSH approved respiratory protection appropriate for exposure potential; self-contained breathing apparatus should be available for emergency use.

Eye Protection: Wear safety glasses (ANSI Z87.1).

Protective Gloves: Wear impervious gloves if the potential exists for dermal contact.

Special Clothing: Wear protective coveralls, whenever the potential for splashing or spraying liquids exists.

Hygiene: Wash hands after handling compound and before eating, smoking, using lavatory, and at the end of the day.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Physical State/Color: 120 ml bottles containing light yellow to dark amber aqueous liquid.

Boiling point: Not available.

Evaporation rate: Not available.

Flash point: Not available.

Freezing point: Not available.

Melting point: Not available.

Octanol/water partition coefficient: Not available.

Odor (threshold): Lemon

pH: 6.0 - 7.6

Solubility in water: Miscible

Specific gravity: Not available.

Vapor density (Air = 1): Not applicable.

Vapor Pressure: Not available.

Viscosity: Not available.



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## 10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions.

Incompatibilities: None known.

Conditions of Reactivity: Not determined.

Hazardous Decomposition Products: CO, CO<sub>2</sub>, HI, I<sub>2</sub> (reddish-brown gas), NO<sub>x</sub>.

Hazardous Polymerization: Will not occur.

Explosion data relative to mechanical impact: Not available.

Explosion data relative to static discharge: Not available.

## 11. TOXICOLOGICAL INFORMATION -- for active ingredients

RTECS NUMBER (U.S.):

LZ4315000 (Diatrizoate Meglumine)

DG6125000 (Diatrizoate Sodium)

### ACUTE

LD50:

Diatrizoate Meglumine:

Acute iv LD50 (rat) = 14,565 mg/kg;

Acute iv LD50 (mouse) = 21,200 mg/kg.

Diatrizoate Sodium:

Acute iv LD50 (rat) = 11,400 mg/kg;

Acute iv LD50 (mouse) = 14,000 mg/kg;

Acute iv LD50 (dog) = 13,200 mg/kg;

Acute iv LD50 (cat) = 11,300 mg/kg;

Acute iv LD50 (rabbit) = 12,200 mg/kg;

Acute im LD50 (mouse) = 20,349 mg/kg.

LC50: No information.

Diatrizoate meglumine and diatrizoate sodium would be classified as essentially nontoxic after acute intravenous injection.

### CHRONIC

Carcinogenicity: See Section 3.

Mutagenicity: No information.

Teratogenicity: When administered intravenously, diatrizoate salts cross the placenta and are evenly distributed in fetal tissues. No teratogenic effects attributable to diatrizoate meglumine or diatrizoate sodium have been observed in teratology studies performed in animals. There are, however, no adequate and well-controlled studies in pregnant women.

Reproductive Effects: It is not known whether Gastrografin can affect reproductive capacity. Diatrizoate meglumine is excreted in breast milk following intravascular exposure.

Toxicological synergistic products: None known.





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## 12. ECOLOGICAL INFORMATION

Ecotoxicological Information: No information.

Chemical Fate Information: No information.

## 13. DISPOSAL CONSIDERATIONS

Disposal: Dispose of in accordance with National, State, Local and applicable country regulations.

## 14. TRANSPORT INFORMATION

### DOMESTIC

Hazard Class (UN NUMBER): Not D.O.T. regulated.  
Proper shipping name: Not applicable.  
Label requirements: Not applicable.  
Placard requirements: Not applicable.  
Limited Quantity Exemption: Not applicable.

### INTERNATIONAL

Hazard Class (UN NUMBER or PIN NUMBER): Not regulated.  
Proper shipping name: Not applicable.  
Label requirements: Not applicable.  
Placard requirements: Not applicable.  
Limited Quantity Exemption: Not applicable.

## 15. REGULATORY/STATUTORY INFORMATION -- not meant to be all inclusive

U.S. Federal: None noted.

International: None noted.

EC Labeling: None noted.

## 16. OTHER INFORMATION

This MSDS was prepared using a new format, and replaces the previous MSDS (10-13-92) for this product.

Persons allergic to diatrizoate salts, iodides, or other components of this formulation should avoid contact to this substance.

Therapeutic agents are intended for use under direction of a physician and/or under the conditions of use described on the label. As a general precaution, personnel who handle drug substances should avoid contact (ingestion, inhalation, skin and eye contact) with these substances.

This material safety data sheet is intended for use by personnel who handle this material as part of their job responsibilities. It does not address the therapeutic use of this material. Information concerning the therapeutic use of this drug substance should be obtained from formulated product package inserts and other appropriate references.

The information contained in this MSDS is believed to be accurate and represents the best information available at the time of preparation. However, we make no warranty, express or implied, with respect to such information, and we assume no liability from its use.